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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,059	09/26/2001	Tony Nick Frudakis	0201-0001	1445
33787	7590	04/19/2004	EXAMINER	
JOHN J. OSKOREP, ESQ. ONE MAGNIFICENT MILE CENTER 980 N. MICHIGAN AVE. SUITE 1400 CHICAGO, IL 60611			KENEDY, ANDREW A	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/964,059

Applicant(s)

FRUDAKIS, TONY NICK

Examiner

Andrew A. Kenedy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

Amendment of original Claims 1, 3-4, 15, 17-18, 29-32, 34-39, 41-43 and 45 in the response filed on March 2, 2004, is acknowledged. Applicants' arguments in the response have been fully considered.

The following rejections and/or objections are either reiterated or newly applied, and constitute the complete set presently being applied to pending Claims 1-45.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 112***

**Claims 29-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.**

Claims 29, 35, 36 and 42 were amended to require "phred-based values". While Applicants' original claims and specification disclose "phred value(s)" and "local phred quality value", they do not disclose "phred-based values". Therefore, this new limitation constitutes NEW MATTER that was not previously disclosed as part of the methods currently claimed.

Claims 29 and 39 were amended to require "end-user input data". While Applicants' original claims and specification disclose "user-defined input value", they do not disclose "end-user input data". Therefore, this new limitation constitutes NEW MATTER that was not previously disclosed as part of the methods currently claimed.

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Claims 29 and 36 were amended to require two new limitations, the first stating that "based on the nucleotide base quality information meeting the predetermined qualification data: causing, by the computer, the nucleotide base position and aligned nucleotide base identifiers at the nucleotide base position to be visually displayed along with a visual prompt for end-user acceptance or rejection" and the second stating that "based on the nucleotide base quality information failing to meet the predetermined qualification data: rejecting the aligned nucleotide base identifiers at the nucleotide base position". While Applicants original claims and specification disclose "visually displaying the nucleotide base quality information for acceptance or rejection", and "if the nucleotide base quality information meets the predetermined qualification data and is accepted, providing and storing resulting data that identifies where the difference amongst the aligned base identifiers exists", they do not disclose the above limitations. Therefore, these added limitations constitute NEW MATTER that was not previously disclosed as part of the methods currently claimed.

Claims 30 and 37 were amended to require a new limitation stating that "based on the nucleotide base quality information meeting the predetermined qualification data: causing, at the computer, a viewing of a sequence chromatogram trace at the nucleotide base position". While Applicants' disclose that "In the sequence within which the discrepancy occurs, position of the minor letters of the discrepancy are presented to the end-user. This lets the end-user contemporaneously call up the raw DNA sequence chromatogram and find the actual trace data peak for the letter", they do not disclose the above limitation. Therefore, this new limitation constitutes NEW MATTER that was not previously disclosed as part of the methods currently claimed.

Claims 32 was amended to require a new limitation stating that "based on the nucleotide base quality information failing to meet the predetermined qualification data: refraining from causing the nucleotide base position and nucleotide base identifiers at the nucleotide base position to be visually displayed along with the visual prompt for end-user acceptance or rejection". While Applicants' disclose that "the quality value information can be checked. If this information is greater than predetermined quality information, such as a user-defined input value, it is accepted and presented to the user for final acceptance. If not, it is discarded", they do not disclose the above limitation. Therefore, this new limitation constitutes NEW MATTER that was not previously disclosed as part of the methods currently claimed.

Claims 34 and 41 were amended to require a new limitation stating that "based on the nucleotide base quality information meeting the predetermined qualification data: causing neighboring aligned nucleotide base identifiers to be visually displayed along with the aligned nucleotide base position". While Applicants' disclose that "if the nucleotide base quality information meets the predetermined qualification data and is accepted, providing and storing resulting data that identifies where the difference amongst the aligned base identifiers exists", they do not disclose the above limitation. Therefore, this new limitation constitutes NEW MATTER that was not previously disclosed as part of the methods currently claimed.

**Claims 1-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.**

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Claims 1 and 15 were amended to include a new limitation that "the set of primer selection rules including a second rule specifying that no primer pair data be identified for that which is found within prestored gene family data with the gene sequence". It seems that one would not know whether or not the primer pair data is present in the prestored gene family data without first identifying its presence in the prestored data. At that point, it is unclear what action should be taken since the method only states that "no primer pair data be identified for that which is found within prestored gene family data", and no positive active step is provided for the situation in which the primer data is identified as being present in the prestored gene family data. If the primer pair data is present and identified within the prestored gene family data, one of ordinary skill in the art would not know how to complete execution of Applicants' method as claimed without additional positive active steps.

**Claims 1-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Claims 1 and 15 were amended by Applicants to include a new limitation that "the set of primer selection rules including a second rule specifying that no primer pair data be identified for that which is found within prestored gene family data with the gene sequence". This limitation is confusing for a number of reasons. First, Applicants' method requires a first step of reading gene sequence data and coding sequence data, however, there is no step in the method for reading "prestored gene family data". Therefore, it is unclear what the prestored gene family data is or where it comes from, thereby rendering the claim indefinite. Second, it is unclear what is meant

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by the phrase "for that which is found" since the term "that" is indefinite and confusing within the context of the limitation. It is unclear whether the phrase refers to sequence data, primer pair data, primer selection rules, or some other data, thereby rendering the scope of the claim uncertain. Third, assuming the above phrase refers to primer pair data, it is unclear how one would know whether or not the primer pair data is present in the prestored gene family data without first identifying its presence, as indicated by the above requirement that "no primer pair data be identified for that which is found". More specifically, it is confusing how the primer pair data can be "found" (which means identified), but to satisfy the entire limitation requirement, not identified.

Claims 4, 18, 43 and 45 require "prestored gene family data" which is indefinite for the reasons given above.

Claim 43 further requires that "no primer pair data be identified for that which is found", which is confusing for the reasons given above.

Claims 29, 35, 36 and 42 require "phred-based values", which is indefinite since the phrase does not have an art understood meaning and no definition is disclosed in the instant application, thereby rendering the scope of the claims uncertain.

#### ***Notice to Applicant***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant is further reminded that deletion of any newly added limitations of the amended claims may result in the reinstatement of previous grounds of rejection.

#### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew A. Kenedy whose telephone number is (571)-272-0574. The examiner can normally be reached on Monday-Friday 9:00am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)-272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.A.K. April 15, 2004

*Marianne P. Allen*

MARIANNE P.  
PRIMARY EXAMINER

4/15/04

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